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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,434	03/24/2004	Noel Coyle	PA1555 CIP1	4253

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MEDTRONIC VASCULAR, INC.
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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
07/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/807,434	COYLE ET AL.	
	Examiner	Art Unit	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,17,18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-5 is rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (US Patent No. 5,833,672). Kawata discloses a catheter (Figs. 9-11), comprising: a proximal shaft (Figs. 9 and 10) defining a guidewire lumen (24; col. 15, lines 32-33) from a proximal end to a distal end thereof and an inflation lumen (22), wherein said inflation lumen is arcuate (Fig. 10 discloses that the inflation lumen 22 is arcuate) from said proximal end to said distal end (Fig. 9) of said proximal shaft; a first reinforcing member (3) and a second reinforcing member (6 is being interpreted as the second reinforcing member just as Applicant discloses that element 372 is a second reinforcing member of Fig. 3c in Applicant's drawings. Currently, Applicant does not further define any other structural limitations of the "second reinforcing member" in claim 2, and just as 372 is a structure that helps to form a lumen and is also a reinforcing member, so too does element 6 as disclosed by Kawata) disposed within said inflation lumen of the proximal shaft; and a distal shaft (Fig. 11) having a guidewire shaft (guidewire lumen 24 runs through the distal shaft) extending from said proximal shaft guidewire lumen to a distal

tip of the catheter such that the catheter has a full-length guidewire lumen (Fig. 11 discloses that the guidewire lumen 24 extends the full length of the catheter), wherein said distal shaft has a greater flexibility that said proximal shaft (col. 3, lines 16-20).

In reference to claim 3, Kawata discloses a transition section (Fig. 11, transition section is labeled 20a) having a proximal end (portion closest to 29) and a distal end (closest to 5), said proximal end communicating with said proximal shaft and said distal end communicating with said distal shaft (Fig. 11).

In reference to claim 4, Kawata discloses that the first and second reinforcing members have a stiffness that is reduced from a proximal end to a distal end of said first and second reinforcing members extending into said transition section (col. 5, lines 23-24 and col. 5, lines 62-67; both members extend the length of the catheter, and therefore extend into the transition section).

In reference to claim 5, Kawata discloses that an outer surface of one of said first and second reinforcing members forms a portion of a surface of the guidewire lumen (Fig. 10).

Claims 6, 9-12, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (US Patent No. 5,833,672). Kawata discloses a catheter (Figs. 9-11) comprising: a proximal shaft (Fig. 11, section 30a) defining a guidewire lumen (Fig. 10, 24) and an inflation lumen (22), wherein said inflation lumen is arcuate shaped (22 is arcuate shaped); a first reinforcing member (9) having a first wall thickness, a first convex surface, and a first concave surface, forming a partial annulus;

a second reinforcing member (6) having a second wall thickness, a second convex surface and a second concave surface, wherein the second reinforcing member is mechanically coupled to the first reinforcing member such that the second convex surface is directed toward the first concave surface so that the combination of the first reinforcing member and the second reinforcing member forms a fluidly sealed tube (Fig. 10); and a distal shaft (Fig. 11, portion 20a) wherein said distal shaft has a greater flexibility than said proximal shaft (col. 3, lines 16-20).

In reference to claims 9 and 10, Kawata discloses that the first and second reinforcing members are polymeric (col. 9, lines 12-17).

In reference to claim 11, Kawata discloses that the first reinforcing member and the second reinforcing member are mechanically coupled together (via element 3). MPEP 2113 recites that "product-by-process claims are not limited to the recited steps, only the structure implied by the steps". Therefore Kawata anticipates claim 11, as it discloses the structure of the first and second reinforcing members being mechanically coupled.

In reference to claim 12, Kawata discloses that the second wall thickness is smaller than the first wall thickness (Fig. 10).

In reference to claims 17 and 18, Kawata discloses that the first and second reinforcing members are made of thermosetting plastic (col. 9, lines 12-17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al. (US Patent No. 5,833,672) in view of Crittenden et al. (US Patent No. 4,988,356). Kawata discloses the device substantially as claimed including: a catheter (Figs. 9-11), comprising: a shaft portion defining a guidewire lumen (Fig. 10, 24) and an inflation lumen (22), wherein said inflation lumen is arcuate shaped (22 is arcuate shaped in Fig. 10); a generally tubular reinforcing member (9) having a first wall thickness, and a cross-section of a partial annulus; and a curved elongated reinforcing member (6) having a second wall thickness smaller than the first wall thickness, wherein the curved reinforcing member is disposed on the first generally tubular reinforcing member such that the combination of the generally tubular reinforcing member and the curved

elongate reinforcing member form the walls of the inflation lumen (22) and an upper surface of the curved reinforcing member forms a portion of the guidewire lumen (24). Kawata, however, does not disclose that the inflation lumen has a longitudinal cut extending radially to the shaft of the guidewire lumen. Crittenden, however, discloses a catheter with a longitudinal cut (Figs. 2 and 5, cut is 28) extending radially from an outer surface of the shaft to the guidewire lumen. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Kawata with the longitudinal cut, as taught by Crittenden, in order to provide a means for inserting or removing an object, such as a guidewire.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawata et al. (US Patent No. 5,833,672). Kawata discloses the device substantially as claimed including first (9) and second (6) reinforcing members (Fig. 10), however, Kawata does not disclose that the reinforcing members are made of metal. It would have been obvious to one of ordinary skill in the art at the time of the invention to have made the first and second reinforcing members of metal in order to provide more rigidity and better reinforcement properties to the catheter, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

The indicated allowability of claims 1, 6-12, 17 and 18 is withdrawn in view of the newly discovered reference(s) to Kawata et al. and Crittenden et al. Rejections based on the newly cited reference(s) follow.

Claims13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments, see after final arguments, filed 6/21/2007, with respect to the catheter not having a guidewire lumen that extends the full length of the catheter have been fully considered and are persuasive. The rejection of claims 2-5 has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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